Declassified/Released US Department of State EO Systematic Review 30 JUN 2005

Message Text

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ORIGIN HEW-04

INFO OCT-01 EUR-12 ISO-00 SCI-04 MED-03 RSC-01 /025 R

66616
DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.
APPROVED BY SCI/SA:MSBEAUBIEN
DHEW/OIH/MACODDING
EUR/NE:SPDAWKINS
---------- 109723
R 112122Z OCT 74
FM SECSTATE WASHDC
TO AMEMBASSY COPENHAGEN

UNCLAS STATE 225155

E.O. 11652: N/A
TAGS: EIND, ETRD, TBIO, DA
SUBJECT: RECALL OF MEDICAL DEVICE - THERMO BLOOD RESERVOIR.

1. FDA ADVISES THAT MED-SCIENCE ELECTRONICS, INC., 1455 PAGE INDUSTRIAL BLVD., ST. LOUIS, MISSOURI 63132 IS RECALLING TO THE USER LEVEL THE FOLLOWING PRODUCT: THERMO BLOOD RESERVOIR, HL-290 BRAND: POLYSTAN HEAT EXCHANGER BLOOD RESERVOIR, SIZE: 1.5 LITER. EACH DEVICE IS CONTAINED IN A STERILE PLASTIC BAG, PRODUCT NO. 057/15/HE CATALOG NO. HL-209 "POLYSTAN A/S SURGICAL PRODUCTS, DENMARK, MFR." THE PRODUCT IS MANUFACTURED BY POLYSTAN A/S SURGICAL PRODUCTS, GENERATORVEJ 41, DK-2730, HERLEV (COPENHAGEN) DENMARK. PRIOR TO JUNE, 1973, THESE DEVICES WERE DISTRIBUTED BY POLYSTAN NORTH AMERICAN, INC., BLOOMINGTON, INDIANA. THIS FORMER DISTRIBUTOR IS NO LONGER IN BUSINESS.

2. THE PRODUCT IS BEING RECALLED BECAUSE SIX UNITS IN POSSESSION OF THE UNIVERSITY OF UTAH LEAKED WATER FROM THE COOLER/HEATER ELEMENT INTO THE BLOOD RESERVOIR, CAUSING THE DEATH OF ONE LABORATORY ANIMAL. TWO UNITS IN POSSESSION OF ST. FRANCIS HOSPITAL, HARTFORD, CONNECTICUT, LEAKED THE CONTENTS OF THE BLOOD RESERVOIR ONTO THE FLOOR IMMEDIATELY AFTER PRIMING THE UNIT'S RESERVOIR WITH LACTATED RINGERS SOLUTION. WHILE NO HUMAN INJURIES HAVE BEEN REPORTED TO DATE, THERE IS A POSSIBILITY
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THAT THIS MEDICAL DEVICE COULD BE USED ON HUMAN PATIENTS.

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3. POST IS REQUESTED TO OBTAIN A COMPLETE LIST OF ALL POSSIBLE CONSIGNEES TO WHOM THIS MEDICAL DEVICE MAY HAVE BEEN DISTRIBUTED TO IN THE UNITED STATES OTHER THAN THE TWO KNOWN DISTRIBUTORS, I.E., MED SCIENCES ELECTRONICS, INC., AND POLYSTAN NORTH AMERICA, INC. SPECIFICALLY, FDA DESIRES TO ASCERTAIN WHETHER THERE HAVE BEEN ANY DIRECT SHIPMENTS FROM THE DANISH FIRM TO ANY OTHER AMERICAN CONSIGNEES. POST IS ALSO REQUESTED TO INFORM HOST GOVERNMENT CONTROL AUTHORITIES OF DEFECTS AND POTENTIAL HAZARD.
INGERSOLL

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